

**Translation**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>433117GA-rp</b>	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. <b>PCT/EP2004/000362</b>	International filing date (day/month/year) <b>19.01.2004</b>	Priority date (day/month/year) <b>21.01.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K 38/17, A61P 35/00</b>		
Applicant <b>RESPONSIF GMBH</b>		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3.	This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4.	This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/000362

Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
  - ☐ publication of the international application (Rule 12.4)
  - ☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ the international application as originally filed/furnished
- ☒ the description:

pages 1-12 \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☒ the claims:
- nos. 1-30 \_\_\_\_\_ as originally filed/furnished

nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☒ the drawings:
- sheets 1/1 \_\_\_\_\_ as originally filed/furnished

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/000362

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)

Claims 1-30

YES

Claims

NO

Inventive step (IS)

Claims 1-30

YES

Claims

NO

Industrial applicability (IA)

Claims 1-30 (see text)

YES

Claims

NO

## 2. Citations and explanations (Rule 70.7)

D1: DE 195 41 284 A (KALDEN JOACHIM ROBERT PROF DR),  
30 May 1996 (1996-05-30)

D2: US 2002/192162 A1 (GREEN ALLAN M), 19 December 2002  
(2002-12-19)

1. The application describes an example of a tumour therapy in which annexin V and interleukin-2 are injected intratumourally into a melanoma and cause the tumour to melt.

The prior art describes only the technical background. It was known before the priority date that cytokines are generally suitable for tumour therapy (see, for example, *Toxicology* 174, 143-152 (2002)).

In the light of the above the subject matter of claims 1 to 30 can be considered novel and inventive.

2. The PCT Contracting States do not have uniform criteria against which the industrial applicability of claims 15 to 30 can be assessed. Patentability may depend on the wording of the claims. For example, the European Patent Office does not recognise the industrial applicability

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/000362

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

of claims to the medical use of a compound. It may, however, allow claims to the first medical use of a known compound or to the use of such a compound in the preparation of a drug for a new medical application.

**Box No. VIII**      **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

3.    Claim 27 is unclear on account of the use of the word "it", which is not defined. Presumably what is meant is "the combination" (see claim 15 on page 3, line 21).
4.    Claims 29 and 30 are unclear on account of the reference to claim 15, because claim 15 makes no mention of tumour cells. The first reference to tumour cells is in claim 27, which means that claims 29 and 30 can only be dependent on claims 27 to 28 or 29.
5.    Claim 30 is unclear on account of the vagueness of the expression "with the protein", which does not indicate what is meant. The term "protein" is not mentioned in any of the back-referenced claims.
6.    Claim 13 (claim 14) can only be dependent on claims 11 and 12 (11 and 13) because the latter refer to tumour cells.
7.    Claims 11 and 12 should probably use the relative pronoun "which" instead of "wherein".